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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,425	03/17/2004	Bonnie L. Bassler	PUNIV.007GEN	3998
26817	7590	10/14/2005		
MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A. 100 THANET CIRCLE, SUITE 306 PRINCETON, NJ 08540				
			EXAMINER WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,425	BASSLER ET AL	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) 49-98 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-48 is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3-17-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-98 are presented for examination.

Applicants' drawings and information disclosure statement filed March 17, 2004 have been received and entered.

Applicants' election filed June 13, 2005 in response to the restriction requirement of April 29, 2005 have been received and entered. The applicants elected the invention described in claims 1-48 (Group I) with traverse.

Applicants' traverse of the restriction requirement is not deemed persuasive for reasons set forth in the previous Office action dated April 29, 2005; therefore, the restriction requirement is hereby made Final.

Claims 49-98 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Allowable Subject Matter

Claims 42-48 are allowable.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,559,176. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches method for identifying a compound that regulates the activity of autoinducer-2 comprising (a) contacting autoinducer-2 with the compound; (b) measuring the activity of autoinducer-2 in the presence of the compound and (c) identifying a compound that regulates the activity of autoinducer-2; and the patented application teaches a method for regulating the activity of an autoinducer-2 receptor comprising contacting an autoinducer-2 receptor with an AI-2 agonist or antagonist compound. Clearly, the patented application is an obvious variant of the present application.

Claim 1 is not allowed.

Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,936,435. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teach a method for identifying an autoinducer-2 analog that regulates the activity of autoinducer-2, comprising (a) contacting a bacterial cell, or extract thereof comprising biosynthetic pathways which will produce a detectable amount of light in response to sutoinducer-2, with the autoinducer analog; (b) comparing the amount of light produced by the bacterial cell,

or extract thereof, in the presence of the autoinducer-2 with the amount produced in the presence of the autoinducer-2 and the autoinducer-2 analog, wherein a change in the production of light is indicative of an autoinducer-2 analog that regulates the activity of autoinducer-2; and the patented application teaches a method for identifying a compound that regulates the activity of an autoinducer wherein said autoinducer is 4,5-dihydroxy-2,3-pentanedione (AI-2) with the same two steps as the present application. Clearly, the present application encompasses the patented application because the present application is broad and the patented application is narrowed.

Claim 10 is not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the autoinducer-2 (4-hydroxy-5-methyl-2H-furan-3-one), does not reasonably provide enablement for other autoinducers-2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates a method for identifying a compound that regulates the activity of autoinducer-2 comprising (a) contacting autoinducer-2 with the compound; (b) measuring the activity of autoinducer-2 in the presence of the compound and (c) identifying a compound that regulates the activity of autoinducer-2; and a method for detecting an autoinducer-associated bacterial biomarker

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comprising (a) contacting at least one bacterial cell with an autoinducer molecule under conditions and for such time as promote induction of a bacterial biomarker; and (b) detecting the biomarker.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for other autoinducers-2 when contacted with a compound

The breadth of the claims

The claims are very broad and inclusive to all autoinducers-2.

The amount of direction or guidance provided and the presence or absence of working examples

The working example is limited to the contacting autoinducer-2 (4-dihydroxy-5-methyl-2H-furan-3-one) with a compound that regulates the activity of the autoinducer-2 and detecting an autoinducer-associated bacterial biomarker.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the other autoinducers-2 when contacted with a compound that regulates their activities. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1-9 and 36-38 are not allowed.

Claims 27-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for bacterial cell is the bacterial strain of the genus *Vibrio*, does not reasonably provide enablement for other bacterial cells or strains.

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The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method for identifying a compound that regulates the production or activity of autoinducer-2, comprising: contacting a

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bacterial cell that produces autoinducer-2 with the compound, and determining whether autoinducer-2 activity is present in the bacterial cell.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the other bacterial cells or strains.

The breadth of the claims

The claims are very broad and inclusive to all bacterial cells or strains (gram-negative and gram-positive).

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the bacterial cell or strain of the genus *Vibrio*.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the other bacterial cells or strains when contacted with the compound will produce autoinducer-2 activity. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 27-35 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is rendered indefinite by the phrase "autoinducer-2 analog" which fails to describe or show what is being meant by the instant phrase. Applicants' claims do not disclose any autoinducer-2 analogs. The remaining claims 11-26 are rendered indefinite to the extent that they incorporate the above terminology.

Claims 10-26 are not allowed.


The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
October 11, 2005